

Amendments to the Claims

Please amend claims 1, 3-10, 12-14, 16-18 and 39 as indicated in the listing of claims.

The listing of claims will replace all prior versions, and listings of claims in the application.

Listing of the claims:

1. (Currently amended) A method for manipulating or formulating a solid substance which melts under pressure of a gas without degrading at a temperature which is lower than the melting point of the substance at atmospheric pressure including comprising:

providing the substance in a pressure chamber having an inlet and an outlet, wherein the outlet is above the inlet;

applying to the substance a liquefied gas or dense gas to melt the substance without degrading the substance;

equilibrating the molten substance and the liquefied gas or dense gas to form a homogeneous solution; and

then contacting the molten substance solution with a carrier fluid, which wherein the carrier fluid is at substantially the same pressure as the liquefied gas or dense gas, to pass form a solution or mixture of at least a part of the molten substance and the carrier fluid; and passing the solution or mixture from the pressure chamber through the outlet into a vessel of lower pressure than the pressure of the liquefied gas or dense gas and carrier fluid to form particles of the substance.

2. (Canceled)

3. (Currently amended) The A method according to of claim 1, wherein the carrier fluid is the same as the liquefied gas or dense gas.

4. (Currently amended) The A method according to of claim 1, further including comprising allowing the substance and the liquefied gas or dense gas to equilibrate for at least one minute before the contacting step.
5. (Currently amended) The A method according to of claim 4, wherein the equilibration step is for a period of about 2 hours.
6. (Currently amended) The A method according to of claim 1, wherein the substance is a pharmaceutical or biological compound.
7. (Currently amended) The A method according to of claim 6, wherein the substance is cyclosporine.
8. (Currently amended) The A method according to of claim 1, wherein the temperature is between 5°C and 150°C.
9. (Currently amended) The A method according to of claim 1, wherein the pressure of the liquefied gas or dense gas and carrier gas is between 5 bar and 200 bar.
10. (Currently amended) The A method according to of claim 9, wherein the liquefied gas or dense gas is carbon dioxide.
11. (Canceled)
12. (Currently amended) The A method according to of claim 1, wherein at least 50% of the particles formed are between 50 and 5000 nanometers in diameter.

13. (Currently amended) The A method according to of claim 1, wherein over 50% of the particles are less than 5000 nanometers in diameter.

14. (Currently amended) The A method according to of claim 1, wherein the particles are encapsulated; ~~the method further including the after the~~ addition of an encapsulating material ~~after the passing of the solution or mixture into a vessel of lower pressure.~~

15. (Canceled)

16. (Currently amended) The A method according to of claim 14, wherein the encapsulating material is biodegradable.

17. (Currently amended) The A method according to of claim 14, wherein the encapsulating material is selected from the group consisting of polyethylene glycol, polyvinylpyrrolidone, poly(d,L-lactide-co-glycolide), poly cellulose acetate.

18. (Currently amended) The A method according to of claim 14, wherein the encapsulated particles contain a mixture or combination of the substance and ~~the a polymer for sustained release applications.~~

19. (Canceled)

20. (Withdrawn) Particles of a substance formed by a method according to claim 1.

21. (Withdrawn) Encapsulated particles of a substance formed by a method according to claims 13.

22. (Withdrawn) Particles according to claims 20, wherein the particles include a pharmaceutical or biological substance.
23. (Withdrawn) Particles according to claim 22 wherein the particles include primarily cyclosporine.
24. (Withdrawn) Particles according to claim 20, wherein at least 50% of the particles are between 50 and 5000 nanometers in diameter.
25. (Canceled)
26. (Withdrawn) A composition suitable for aerosol delivery including particles formed by a method according to claims 1.
27. (Withdrawn) A method of treatment of a subject including administering to the subject an effective amount of fine particles of a substance produced by a method according to claim 1.
28. (Withdrawn) A method according to claim 27 wherein the substance is a pharmaceutical or biological compound.
29. (Withdrawn) A method according to claim 27 wherein the administration of the substance is by inhalation.
30. (Withdrawn) A method according to claim 24 wherein the administration is by transdermal application, oral, controlled or sustained release.

31. (Withdrawn) An apparatus for producing particles by the method according to claims 1, including:

a pressure chamber having an inlet and an outlet, the outlet being above the inlet;
a first conduit means connected to the inlet for supplying the liquefied gas or dense gas to the pressure chamber; and
a second conduit means extending from the outlet to a depressurisation point.

32. (Withdrawn) An apparatus according to claim 31, further including flow control means to control flow along the second conduit means.

33. (Withdrawn) An apparatus according to claim 32, further including a third conduit means connected to the downstream end of the second conduit means downstream of the flow control means for supplying liquefied gas or dense gas, or carrier fluid, at pressure to the depressurisation point.

34. (Canceled)

35. (Withdrawn) An apparatus according to claims 33, wherein the apparatus upstream of the depressurisation point is maintained at a constant temperature by a temperature bath.

36. (Withdrawn) A pharmaceutical composition including particles of a substance produced by a method according to claims 1.

37. (Withdrawn) A pharmaceutical composition according to claim 36, wherein the substance is a pharmaceutical or biological compound.

38. (Withdrawn) A pharmaceutical composition according to claim 36, wherein the substance is cyclosporine.
39. (Currently amended) The A method ~~according to~~ of claim 6, wherein the substance is gemfibrozil or fenofibrate.
40. (Withdrawn) Particles according to claim 20 wherein the particles include primarily gemfibrozil or fenofibrate.
41. (Withdrawn) A pharmaceutical composition according to claim 36, wherein the substance is gemfibrozil or fenofibrate.